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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,106	09/25/2003	Michael E. O'Donnell	22221/1150 (RU-339)	7285

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Nixon Peabody LLP
Clinton Square
P.O. Box 31051
Rochester, NY 14603-1051

EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/671,106

Applicant(s)

O'DONNELL ET AL.

Examiner

Richard G. Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 6-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17-21 is/are allowed.
- 6) ☒ Claim(s) 1,2 and 6-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment of 1, cancellation of claims 3-5 and the addition of new claims 10-21, in the paper of 9/11/2006, is acknowledged. Claims 1, 2, 6-21 are at issue and are present for examination. Applicants' arguments filed on 9/11/2006, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2 and 6-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection was stated in the previous office action as it applied to previous claims 1-9. In response to this rejection, applicants have amended claim 1, cancelled claims 3-5 and added new claims 10-21 and traverse the rejection as it applies to the newly amended claims.

Applicants traverse the rejection on the basis that the burden of establishing that an application lacks written descriptive support falls on the PTO and that this cannot be founded upon the basis of genus size alone. Applicants submit that this is the position

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that the PTO has taken on pages 3-4 of the previous office action and applicants present exhibits 1-3 as evidence that the nucleic acid sequence of SEQ ID NO: 179 and the corresponding amino acid sequence of SEQ ID NO: 180 represent the claimed genus. Applicants present Genbank accessions for *Bacillus holB* nucleic acids that are homologous to the nucleotide sequence of SEQ ID NO: 179. Applicants submit that the alignment of these sequences supports that the delta prime subunits of a DNA polymerase III-type enzymes from *Bacillus* share similar structure and therefore function.

Applicants further submit that the language recited in claims 1 and 9 is precisely the type of claim language that was acknowledged in *Univ. of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) as being acceptable under written description requirement.

Applicants further submit that the "Guidelines for Examination of Patent Applications Under 35 USC 112 1st Paragraph, 'Written Description Requirement' make explicitly clear that the description of a representative number of species does not require the description to be of such nature that it would provide support for each species that the genus embraces.

Applicants thus submit that based upon the above, the previous conclusion by the PTO is contrary to evidence submitted herewith by applicants and that one of ordinary skill in the art would have understood that applicants were in possession of the presently claimed invention.

Applicant's amendment and arguments are acknowledged and have been carefully considered, however, have been found to be non-persuasive in overcoming the instant rejection based upon a lack of written description. While applicants argue that the presently claimed genus shares similar structure and thus function based upon this "similar structure", this conclusion remains in question. Applicant's claims are drawn to those nucleic acids encoding a delta prime subunit of a DNA polymerase III-type enzyme and this "function" in combination with the structural limitations of the claims is insufficient to meet the requirement for the written description of the claimed genus. It remains that applicants have not adequately described a structure-to-function relationship given that the "function" of the claimed nucleic acids remains in question. What is the function associated with a delta prime subunit of a DNA polymerase III-type enzyme and how does it relate to referred to structure?

Applicants comparison to the decision in the Univ. of California v. Eli Lilly, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) is acknowledged, however, as stated above, the recited function in the instantly claimed genus remains not as clear as that in the referred to case law, and thus any comparison to a decision based upon this is considered flawed.

Finally, applicants submission that the "Guidelines for Examination of Patent Applications Under 35 USC 112 1st Paragraph, 'Written Description Requirement' make explicitly clear that the description of a representative number of species does not require the description to be of such nature that it would provide support for each species that the genus embraces, is acknowledged, however, given the necessary

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function of the encoded proteins, it remains that a sufficient structure-to-function relationship has not been established for the currently claimed genus.

Applicant is referred to the guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1, 2 and 6-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated DNA molecule encoding a delta prime subunit of a DNA polymerase III-type enzyme, comprising the nucleotide sequence of SEQ ID NO: 179, does not reasonably provide enablement for any DNA molecule encoding any "delta prime subunit of a DNA polymerase III-type enzyme" from any *Bacillus* species, hybridizing to the complement of SEQ ID NO: 179 under conditions comprising 0.9M sodium citrate buffer at a temperature of 37°C. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection was stated in the previous office action as it applied to previous claims 1-9. In response to this rejection, applicants have amended claim 1, cancelled claims 3-5 and added new claims 10-21 and traverse the rejection as it applies to the newly amended claims.

Applicants submit that applicants provide the nucleotide sequence of *Bacillus stearothermophilus holB* and applicant's specification describes how one of ordinary

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skill in the art can isolate homologs of the disclosed sequence, express the encoded protein and test for the proper activity. Thus one of ordinary skill in the art would have been fully enabled to make and use the DNA molecules and their encoded protein.

Applicants complete argument is acknowledged, however, is found non-persuasive for the reasons previously made of record and because applicants have not presented sufficient guidance as to the required function of the encoded proteins with respect to "a delta prime subunit of a DNA polymerase-III type enzyme". Thus it remains that one of ordinary skill in the art would not be able to screen for such an activity, much less make and use a majority of those encompassed DNA molecules.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any DNA molecule encoding a "delta prime subunit of a DNA polymerase III-type enzyme" from any *Bacillus* species, because the specification does not establish: (A) regions of the DNA and encoded protein structure which may be modified without effecting "delta prime subunit activity"; (B) the general tolerance of a delta prime subunit of a DNA polymerase III-type enzyme and encoding DNA to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue and the encoding nucleotide sequence of a delta prime subunit of a DNA polymerase III-type enzyme with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. Because of this lack of guidance, the extended experimentation

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that would be required to determine which substitutions would be acceptable to retain the delta prime binding activity claimed and the fact that the relationship between the sequence of a peptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable (, it would require undue experimentation for one skilled in the art to arrive at the majority of those DNA molecules of the claimed genus encoding a protein having the desired activity.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any DNA molecule encoding a delta prime subunit of a DNA polymerase III-type enzyme from any *Bacillus* species, hybridizing to the complement of SEQ ID NO: 179 under conditions comprising 0.9M sodium citrate buffer at a temperature of 37°C. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those DNA molecules having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Richard G. Hutson', is written over a horizontal line.

Richard G Hutson, Ph.D.
Primary Examiner
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rg
11/27/2006